Policy Makers' Paradigms and Evidence from Consumer Interpretations of Dietary Supplement Labels

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New Era at the FDA

- 1994 Dietary Supplement Health Education Act (DSHEA)
- 1999 Pearson v. Shalala
- 2003--FDA undertook initiatives to improve consumer information with the goal of "smarter decisions about the foods they eat."
- "Recent court decisions have clarified the need to provide for health claims based on somewhat settled science rather than just on the standards of significant scientific agreement, as long as the claims do not mislead the consumer."

Purpose of the Current Study

- Empirically examine the consumer's information environment
- Examine two paradigms of consumer information processing:
  - Direct effects model
  - Impact of consumer filters

Existing Literature

- Disclaimers
  - May not have intended effect (Depends on consumer's ability to comprehend, message believability, relevance…Stewart and Martin 1994, Ford, Hastak, Mitra and Ringold 1996)
  - Absolute disclaimers less effective than those identifying specific risk; effectiveness a function of knowledge (nutrient content claims; Andrews, Burton and Netermeyer 2000; Andrews, Netermeyer and Burton 1998)
  - Disclaimers must be very carefully and strongly worded—may have an effect opposite that intended (food advertising disclaimers; Murphy and Hoppock 1998)

Nature of Claims and Disclaimers

- Structure Function Claims:
  - Designed to inform consumers that the product supports a particular body function
  - THEREFORE – should not lead a consumer to believe that the product prevents, treats, cures a disease

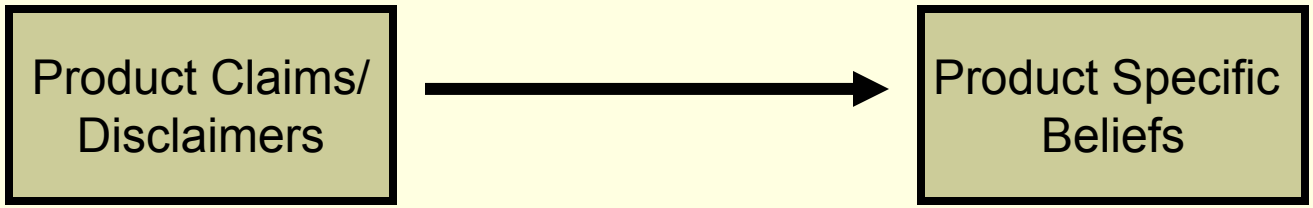
- DSHEA Disclaimer:
  - Should insure that consumers understand that the FDA has not evaluated the claim and should reduce the belief that the product has the ability to prevent, treat or cure a disease

Nature of Claims and Disclaimers

- Disease Claims:
  - Implies or specifically indicates a relationship between the supplement and a particular disease or disorder
  - THEREFORE – may lead a consumer to believe that the product prevents, treats, cures a disease

- Scientific Evidence Disclaimer:
  - Deals with “emerging science” and specify the preliminary scientific evidence of a relationship between the supplement and the disease or disorder
  - THUS, the information in this disclaimer contradicts the primary disease claim being made.

DIRECT EFFECTS MODEL

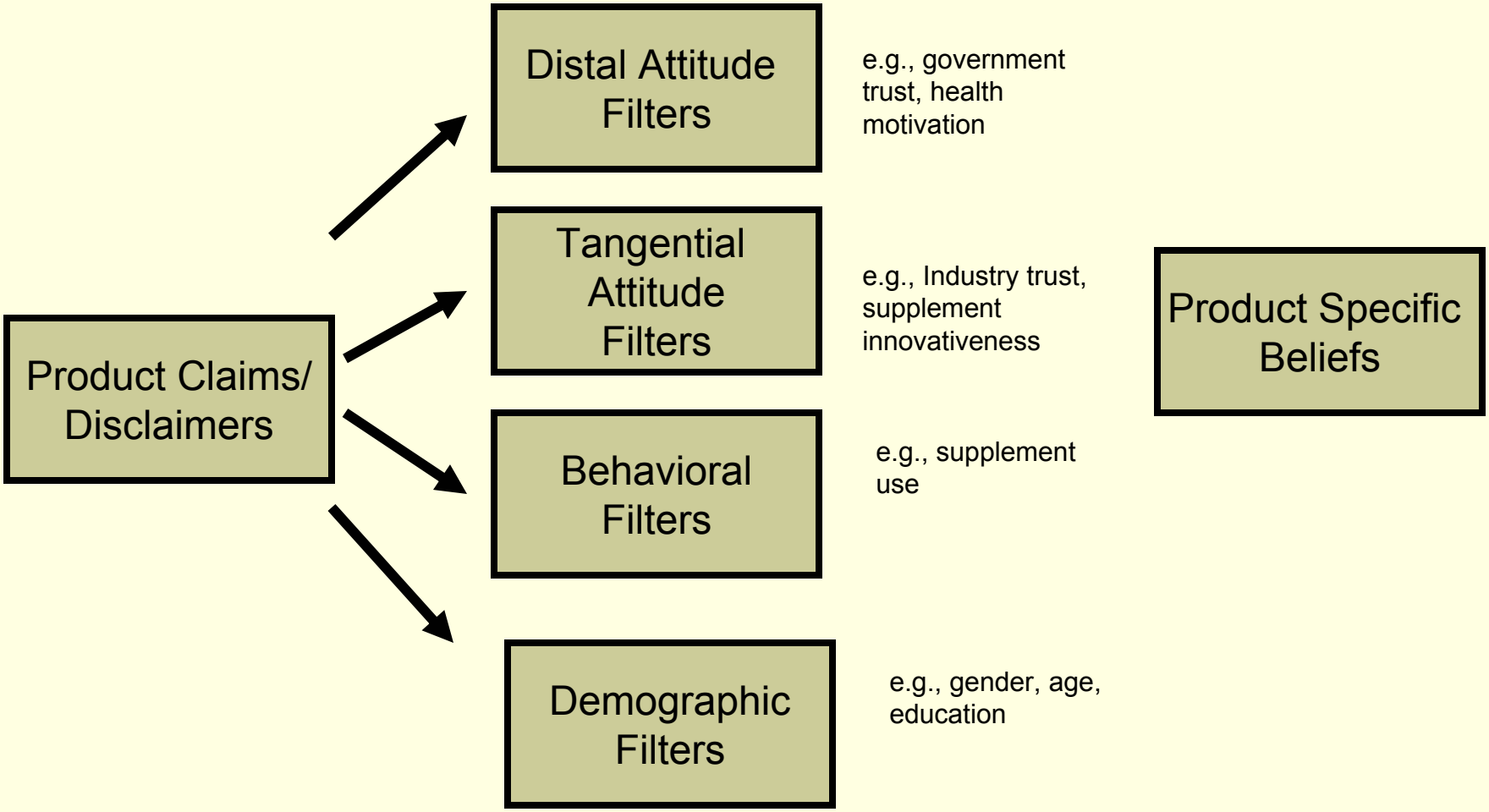


- Consumer beliefs should be significantly affected by information on the label
- Such beliefs reflect differences between the type of claim and disclaimers used

The Impact of "Filters" on Consumer Beliefs

- The meaning derived from claims/disclaimers depends on information processing factors including biasers derived from preexisting beliefs and demographics
- Confirmatory Bias
  - Consumers interpret structure function and disease claims and disclaimers in a manner that confirms an existing belief (Chernev 2001, Deighton 1984, Hoch and Ha 1986, Russo, Meloy and Medvec 1998)
  - Arise because consumers are motivated to maintain consistency in their beliefs

The Impact of "Filters" on Consumer Beliefs



Method

- 2 supplements
  - Garlic (well-known supplement)
  - Herb X (unknown supplement)
- 5 claim/disclaimer combinations
  - Structure function claim only (no disclaimer)
  - Structure function claim with DSHEA disclaimer
  - Disease claim only (no disclaimer)
  - Disease claim, short post-Pearson scientific evidence disclaimer
  - Disease claim, post-Pearson scientific evidence disclaimer
- No claim/disclaimer control for garlic supplement

Structure function claim only: Garlic (Herb X) maintains a health circulatory system.

Structure function claim with DSHEA disclaimer: This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Disease claim only: The consumption of Garlic (Herb X) may reduce the risk of coronary heart disease.

Disease claim, short disclaimer: The scientific evidence about whether Garlic (Herb X) may reduce the risk of Coronary Heart Disease (CHD) is suggestive, but not conclusive.

Disease claim, long disclaimer: The scientific evidence about whether garlic may reduce the risk of Coronary Heart Disease (CHD) is suggestive, but not conclusive. Studies in the general population have looked at diets containing garlic and it is not known whether diets or garlic in food may have a possible effect on a reduced risk of CHD. It is not known what effect garlic may or may not have on the risk of CHD in the general population.

Dependent Measures

- Structure Function Beliefs: (average of 2 six-point items, "not at all likely" to "very likely"; α=0.84)
  - How likely is it that garlic (herb X) supplements help keep a person's heart healthy?
  - How likely is it that garlic (herb X) supplements keep a person's heart functioning in a healthy way?

- Disease Beliefs: (average of 3 six-point items, "not at all likely" to "very likely"; α=0.84)
  - How likely is it that garlic (herb X) supplements help cure heart disease?
  - How likely is it that garlic (herb X) supplements help prevent heart disease?
  - How likely is it that garlic (herb X) supplements help to reduce the symptoms of heart disease?

Dependent Measures cont'd

- Scientific Certainty (2 individual six point items, "very unsure" to "very sure")
  - How sure are scientists that taking garlic (herb X) will help maintain a healthy heart?
  - How sure are scientists that taking garlic (herb X) will reduce the risk of heart disease?

- FDA Evaluation: (average of 2 five-point "strongly disagree" to "strongly agree; alpha = 0.88).
  - People at the FDA have checked that the statements about garlic (herb x) supplements on the package are true.
  - The FDA agrees that Garlic (herb X) supplements maintain a healthy heart function.

Procedures

- Mall intercepts at 7 geographic locations
- Quota sampling to match US Bureau of Census projections for age (n= 359)
- Subjects completed verbal protocol, self administered questionnaire (dependent and personal difference measures)
  - Trust in government (Scholz and Lubell 1998)
  - Health-motivation (Moorman and Matulich 1993)
  - Trust in the herbal dietary supplement industry (patterned after Mohr, Eroglu and Ellen 1998)
  - Supplement innovativeness (Goldsmith and Hofacker 1991)
  - Supplement use
  - Demographic characteristics
- Label in full view while subjects complete questionnaire. No need to recall information.
- Contrasts and MANCOVA used

Findings

- H1: Consumer beliefs regarding the effectiveness of a supplement in preventing, treating or curing a disease are lower when exposed to a structure function claim than when exposed to a disease claim.
- Non-significant Wilks' Λ for label and claims condition → disease beliefs do not vary by type of claim
- No difference in disease beliefs for structure function claim only and disease claim only for both garlic (p=0.51) and herb X (p=0.55)
- No Support for H1

- H2: Consumer beliefs regarding whether the FDA evaluated the statements made on the package label are lower when the DSHEA disclaimer is used on the package label than when it is not used on the package label.

- No difference in FDA evaluation for structure function claim only and structure function claim with DSHEA disclaimer for both garlic ($p=0.11$) and herb X ($p=0.56$)

- No Support for H2

- H3: Consumer beliefs regarding the effectiveness of the supplement in preventing, treating or curing a disease are lower when the DSHEA disclaimer is used on the package label than when it is not used on the package label.

- No difference in disease beliefs for the structure function claim only and structure function claim with DSHEA disclaimer for both garlic (p=0.99) and herb X (p=0.39)

- No Support for H3

- H4: Consumer beliefs regarding the scientific certainty about the relationship between a particular disease and a particular supplement are lower when the scientific certainty disclaimer is used on the package label than when it is not used on the package label.
- Contrasts between the disease claim only and the short/long scientific evidence disclaimer show no difference in the scientific certainty scores for both garlic (all p's > 0.15) and herb X (all p' >0.39)
- No Support for H4

- H5: Consumer beliefs regarding the effectiveness of a dietary supplement in preventing treating or curing a particular disease are lower when the scientific certainty disclaimer is used on the package label than when it is not used on the package label.

- Contrasts between the disease claim only and the short/long scientific evidence disclaimer show no difference in consumer disease beliefs for both garlic (all p's > 0.50) and herb X (all p' >0.25)

- No Support for H5

THUS:

- WE FIND VERY LITTLE SUPPORT FOR THE "DIRECT EFFECTS" MODEL

Examining the FILTERS MODEL:

- H6: There is a significant interaction between the claims/disclaimers and the supplement name such claims/disclaimers have less impact on consumer beliefs regarding the supplement's effectiveness, the scientific certainty and the FDA evaluation of the claims on a well-known dietary supplement than on an unknown supplement.
- Non-significant Wilks' Λ this interaction
- For herb X, no significant differences between cells in structure function beliefs nor disease beliefs
- No Support for H6

Impact of Distal Attitudinal Filters

- H7: Consumers with high levels of trust in the government believe that the government is evaluating the dietary supplements, regardless of the disclaimer statements.
- Government trust is positively related to beliefs about FDA evaluations.
- H8: Consumers concerned with preventing health problems believe that the supplement supports a particular body function and is more effective in preventing, treating and curing a particular disease.
- Health motivation is positively related to both structure function beliefs and disease prevention beliefs.
- Support for H7 and H8

Impact of Tangential Attitudinal and Behavioral Filters

- H9: Consumers with pre-existing positive (negative) beliefs and behaviors regarding the dietary supplement industry believe that a particular supplement is more (less) effective than those with pre-existing negative (positive) beliefs and behaviors
- Industry trust and dietary supplement innovativeness are positively related to both structure function and disease beliefs.
- Supplement use is significantly related to disease beliefs: believe that the supplement is effective in curing, preventing and reducing symptoms AND believe that the FDA has evaluated claims
- Support for H9

Impact of Demographic Filters

- H10: Gender, age and education serve as a filter through which information is processed.
- Only education is significantly related to consumer beliefs:

  higher education → lower disease belief scores
  lower scientific certainty scores
  lower belief in FDA evaluation

- Partial support for H10

How strong are these filters?

Dependent variable	R^2
Structure function beliefs	0.30
Disease beliefs	0.35
Scientific agreement: structure function	0.23
Scientific agreement: disease	0.25
FDA evaluation	0.34

Discussion/Conclusion

- In the context of this study:
  - Structure/function claims lead to equivalent beliefs as disease claims
  - DSHEA disclaimer did not not effectively lower beliefs regarding FDA evaluation nor beliefs regarding product efficacy
  - Scientific evidence disclaimers had no effect on consumer's scientific certainty score
- THUS: Claims and disclaimers appear to be ineffective in reaching consumer knowledge goals.

Beliefs were significantly affected by biasing filters:

- Government trust
- Health motivation
- Industry trust
- Dietary supplement innovativeness
- Supplement use
- Education

- Broadens perspective of Confirmatory Bias theory
  - Disturbing that those who use and thus, most exposed to the claims and disclaimers are least effected by the package claims/disclaimers

Bounds of the research

- Situational involvement—task at hand
  - Priming of relevance
  - Specific attention measures
  - Attenuated due to label simplicity? Or did simplicity maximize the effects?
- Enduring involvement
  - 6% have heart disease
  - 3% use garlic
  - What if members of the subject pool suffered from chronic illness related to claim/disclaimer?

Thank you!